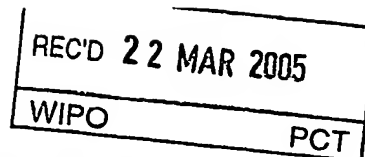


PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference 11876-23PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/CA 03/01213	International filing date (<i>day/month/year</i>) 08.08.2003	Priority date (<i>day/month/year</i>) 08.08.2003
International Patent Classification (IPC) or both national classification and IPC A61L27/06		
Applicant BIORTEX INC. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains Indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 22.02.2005	Date of completion of this report 21.03.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Peris Antoli, B Telephone No. +49 89 2399-8476

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CA 03/01213

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-23 as originally filed

Claims, Numbers

1-12 as originally filed

Drawings, Sheets

1/5-5/5 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
 - ☐ the language of publication of the international application (under Rule 48.3(b)).
 - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
- ☐ contained in the international application in written form.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority in written form.
 - ☐ furnished subsequently to this Authority in computer readable form.
 - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
 - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/CA 03/01213**

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-12
	No: Claims	
Inventive step (IS)	Yes: Claims	1-12
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-12
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: US-A-5 986 169

D2: US-A-2002/0062154

2. Claims 1-12 meet the requirements of Art. 33(2) and 33(3) PCT because their subject matter is new and inventive over the prior art documents cited in the search report (see below).

2.1 Novelty:

- 2.11 None of the prior art documents cited in the search report discloses porous nickelide titanium (TiNi) material comprising a porous matrix of TiNi characterized, among others, in that it includes up to 10 atomic % oxygen with the balance being Ti and Ni, the maximum Ni content being 53% atomic,.

- 2.12 Thus, the subject matter of the main claim 1 and that of its dependent or related claims 2-12 is new over the referred prior art.

2.2 Inventive step:

- 2.21 The problem posed in the present application (see p. 2, I. 12-16) was to provide porous TiNi material having biochemical and biomechanical properties compatible with bone and with a porosity sufficient to permit bone integration.

- 2.22 As proposed in the claims said problem is solved with a porous TiNi matrix having a porosity as specified in claim 1 which, apart from having specific amounts of Ni and Ti, also includes up to 10 atomic % oxygen and which is further devoid of Ni-enriched secondary phases.

[As indicated in the description (see e.g. working examples) said matrices can be prepared by means of the Self-propagating High temperature (SHS) technique followed by elimination of peripherally formed Ni-enriched secondary phases or by annealing to avoid formation of said Ni-enriched secondary phases].

2.22 Porous TiNi matrices having a porosity as specified in claim 1 and their preparation using the (SHS) technique are already known from the state of the art. With this respect see e.g. **D1** (claims 1, 3-5, 12 and c. 3, l. 47-60) or **D2** (§ [0052] or § [0118] in conjunction with Table 1 on p. 7).

D1 (see e.g. c. 2, l. 12-18 and 64-67; and examples 3-4) and **D2** (see e.g. § [0053], § [0092], [0156], § [0172], [0176] or [0251]) also teach the utility of the referred porous TiNi matrices as biomedical implants, including bone implants, due to their biocompatibility and their physiomechanical properties which are similar to those of bone,. are already known from the sate of the art. With this respects see e.g.

2.24 However, the experimental data of the present application (see Tables 8-10) evidence that porous TiNi material according to the present invention exhibits better mechanical properties (for compatibility with bone) than porous TiNi material according to the prior art, including porous material according to D1 (see Table 10).

2.25 Since said better mechanical properties could not have been foreseen from the teachings of the prior art cited in the search report, the claimed subject matter is considered to be inventive.

INDUSTRIAL APPLICABILITY:

3. Claims 1-12 satisfy the criterion set forth in Art. 33(4) PCT because their subject matter is susceptible of industrial application.